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Summary & Certification

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Summary of safety and effectiveness

Log-a-Rhythm Model 100 is a cardiometer and ECG recorder. It is completely non-invasive and is operated with two 9 Volt batteries. Use of Log-a-Rhythm Model 100 poses no hazards, electrical, chemical, or physical, to the patient. Log-a-Rhythm is effective in accurately measuring and storing consecutive beat-to-beat intervals during sinus rhythm. Its accuracy in measuring intervals was tested using the American Heart Association ECG database, which has been scored by medical experts. Concordance of Log-a-Rhythm with the scored values was better than 97 percent. Log-a-Rhythm display software calculates, displays, and optionally prints the heart rate and RR interval data using a computer with a 80386 processor or higher.